

Operator's Manual

Flo-Gard® 6300

Dual Channel Volumetric Infusion Pump

Product Code: 2M8048

Baxter

Introduction

The Baxter Flo-Gard® 6300 Dual Channel Volumetric Infusion Pump can deliver a wide variety of fluids over a broad range of infusion rates. The device's features include:

- Uses standard Baxter solution administration sets.
- Two separate pump channels which allow the Flo-Gard® 6300 device to do the work of two conventional pumps, resulting in space savings.
- Easy to load, spill-resistant pump mechanisms.
- Pumps a wide variety of fluids, including blood.
- Occlusion sensors that detect both upstream and downstream restrictions.
- Flow check information display that shows resistance to flow.
- Ultrasonic air-in-line detectors.
- Safety clamp mechanisms which prevent accidental free flow.
- Locking control panel which prevents tampering.
- Each pump channel features an independent secondary medication program that automatically switches over to the primary program upon completion.
- Volume-Time programming that automatically calculates flow rate.
- Automatic self-test routine that checks for proper function before use.
- Five hour memory which retains infusion data after power-off.
- Easily replaceable fuse, battery, and power cord.

Physical Description (continued)

| ITEM | FUNCTION |
|-------------------|---|
| 22. SEC START Key | Starts the delivery of the secondary solution for the selected pump. |
| 23. CHARGING LED | Green LED, always lit while the unit is plugged in and the battery is charging. |

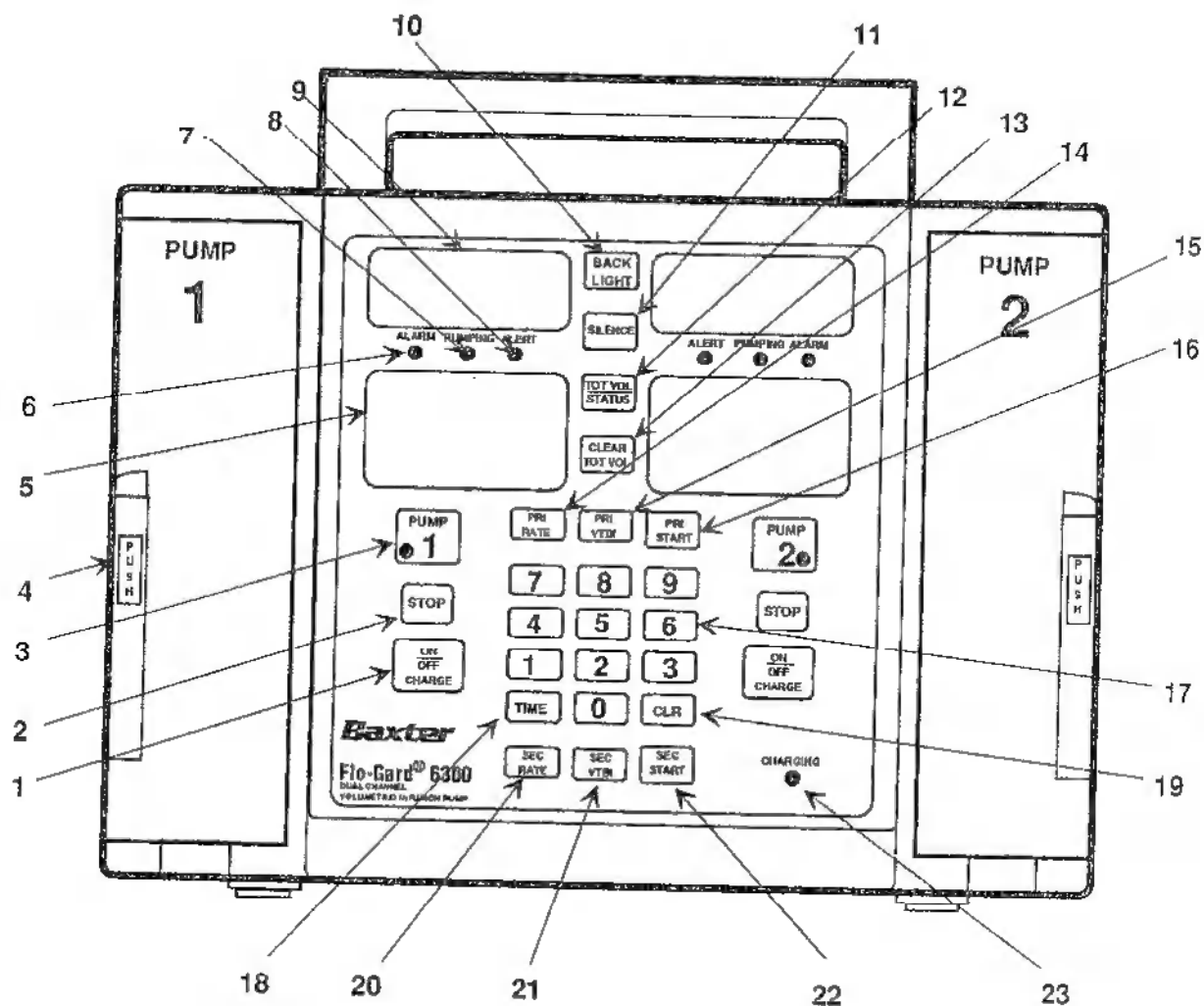


Figure 1. Front View

Pump Features

Figure 2 shows Pump 2 only. Pump 1 has identical features, which function in the same manner.

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|--------------------------------|--|
| 1. Upstream Occlusion Sensor | Detects a complete tubing restriction upstream of the pump. |
| 2. Pump Mechanism | Linear peristaltic pump mechanism. |
| 3. Downstream Occlusion Sensor | Detects tubing restrictions downstream of the pump. |
| 4. IV Set Loading Diagram | Identifies the IV set loading path in the pump. |
| 5. Air Sensor | Detects air bubbles in the IV tube. |
| 6. SAFETY CLAMP | Prevents accidental fluid flow when the pump door is opened. |

The following items are located on the rear of the Flo-Gard® 6300 device and are shown in Figure 3.

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|------------------------------------|--|
| 1. IV Pole Clamp | Secures the Flo-Gard® 6300 device to the IV pole. |
| 2. Power Cord Clips | Store power cord during battery operation and device storage |
| 3. FUSE | Fuse compartment. |
| 4. Power Cord | Removable only by authorized service personnel. |
| 5. Audio Speakers | For generation of audible alarm and alert beeps. |
| 6. SERVICE PORT | For authorized service personnel use only. |
| 7. COMMUNICATIONS PORT | Reserved for future use. The communications port contains nurse call connections which can be enabled by authorized service personnel. |
| 8. PANEL LOCK Switch | When pressed, it disables front panel controls, except BACKLIGHT and TOT VOL/STATUS. |
| 9. VOLUME Knob | Adjusts loudness of audible alarm and alert beeps. The beeps cannot be turned completely off. |
| Battery Compartment (Not shown) | Allows easy access to the battery by authorized service personnel only. Located on the underside of the Flo-Gard® 6300 device. |

the Audible Switchover option is selected, the message AUDIBLE SWITCHOVER appears in the Pump 2 message display at the same time.

c. If Auto Restart and Flow Check are enabled, the message AUTO RESTART appears for one second following the occlusion detection level display in the Pump 1 message display.

d. Three separate audible tones sound.

e. If the Flo-Gard® 6300 device is plugged into an AC outlet, the CHARGING LED is illuminated.

12. Set VOLUME knob on the rear of the device to the desired level.

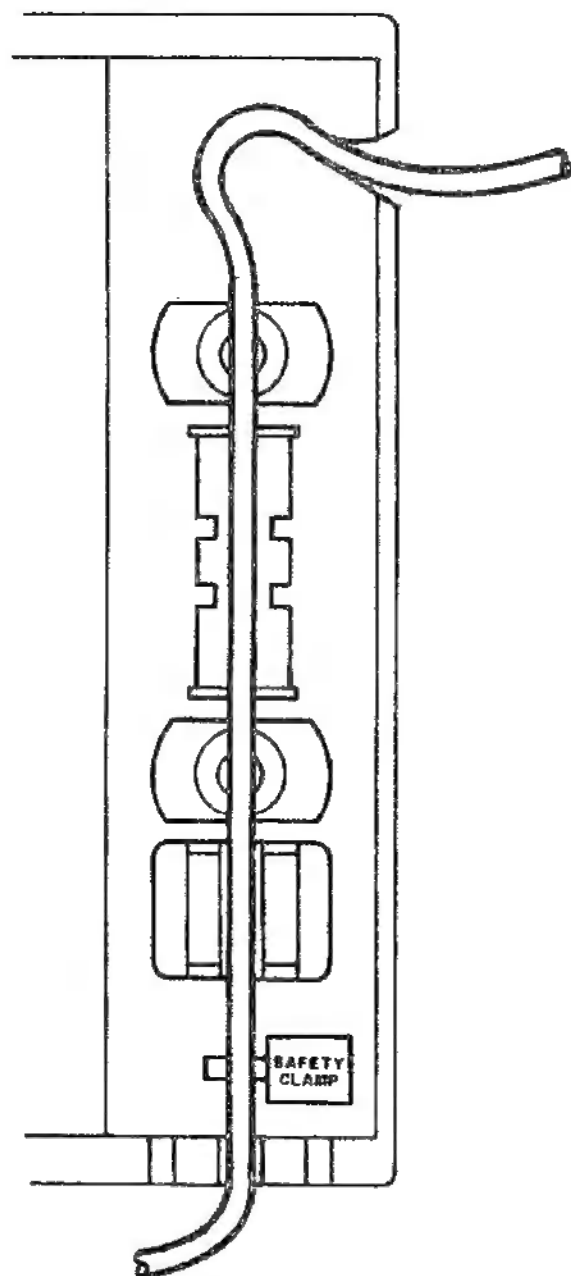


Figure 4. IV Set Loading Diagram

Programming the Pumps (continued)

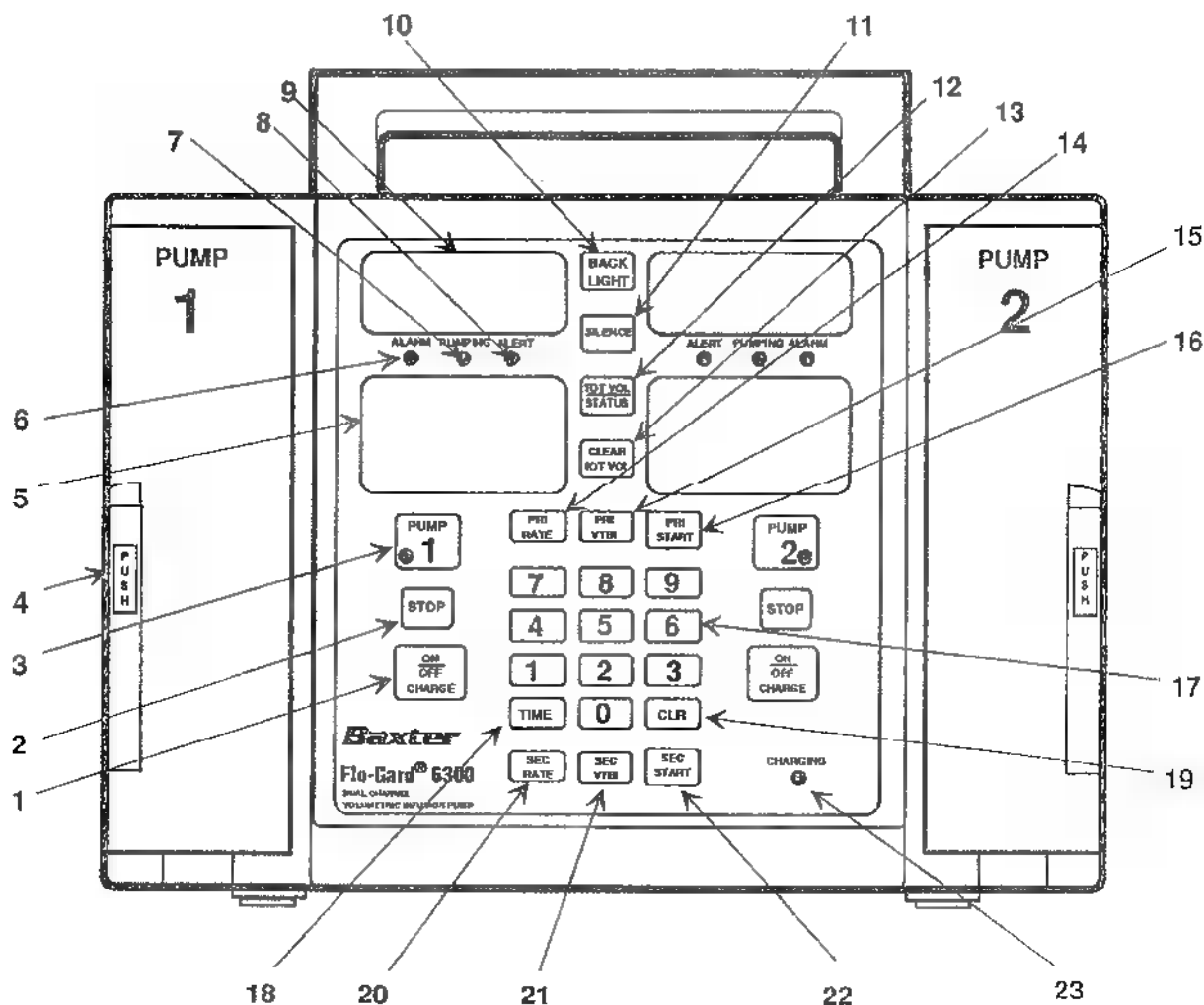


Figure 5. Front View

Starting A Secondary Program

Note: The procedures for programming a secondary infusion are identical for Pump 1 and Pump 2.

1. Prepare secondary fluid container and administration set according to the directions accompanying the products. Ensure all air is expelled from the secondary set. To perform automatic piggybacking, a Continu-Flo® set from Baxter should be used as the primary set.
2. With the selected pump stopped and the primary program already entered, attach the secondary set to the injection site of the primary set above the device.
3. Lower primary container with the hanger accompanying the Baxter secondary set.

7. Verify that the calculated rate is acceptable before pressing PRI START (or SEC START) to begin the infusion.

Changing Flow Rates (Titrating) While Pump Is Running

To change the primary or secondary flow rate, follow the procedure given below.

1. Press PUMP 1 or PUMP 2 as appropriate to select the desired pump.
2. Press PRI RATE while pump is running in primary mode. TITRATE appears in the selected pump's message display and an alert beep sounds periodically.
3. Enter the new flow rate on the keyboard. If the primary is titrated above 999 mL/hr, ensure that the secondary set on/off clamp is closed. If a new rate higher than the allowable maximum is entered, the message "HI" appears in the PRI RATE display.
4. Press PRI START. The pump begins delivering fluid at the new rate, the alert beep stops, and the TITRATE message disappears.
5. To change secondary flow rate, follow the above procedure using the SEC RATE and SEC START keys instead of the PRI RATE and PRI START keys.

Locking The Front Panel

The device front panel can be locked during pumping to prevent tampering. It can be unlocked at any time. The TOT VOL/STATUS and BACK LIGHT keys are not affected by the lock-out. This allows routine infusion data checks while the front panel is still locked. If either pump is stopped due to an infusion alarm or an opened door, the panel must be unlocked to restart the infusion.

To lock the panel: While pump(s) is running, press the PANEL LOCK switch on the rear of the device for at least one second. The message 'Loc' appears in the main display of pumps that are powered on.

To unlock the panel: Press the PANEL LOCK switch again. The 'Loc' message disappears.

Battery Powered Operation

The Flo-Gard® 6300 device automatically switches to battery operation when the AC power is interrupted or the device is unplugged. When operating on battery power, BATTERY appears in the Pump 2 message display. The battery automatically recharges whenever the device is plugged in. It is recommended that the device be plugged into an AC outlet during storage to help maintain batteries at full charge. Any Pump 2 alarm or alert messages will supersede the BATTERY display.

Alerts and Alarms

The following chart describes each pump's alarm and alert messages along with the cause of each.

| Alert Message | Flow Status | Alert Condition |
|--|---------------------------------------|---|
| STOPPED | No flow | Pump has been in STOPPED mode for two minutes. |
| KVO PRI VTBI =0 | KVO | Primary VTBI has been delivered. The pump has switched to a KVO rate of 5 mL/hr or programmed rate, whichever is less. |
| TITRATE | No change until procedure is complete | Flow rate is being changed while pump is running. Pump will remain in TITRATE alert condition until the appropriate START key is pressed. |
| PRI RATE =0 | No flow | A primary flow rate of zero has been entered. The pump will remain in this alert condition until a non-zero primary flow rate is entered and the PRI START key is pressed. |
| BATTERY LOW with intermittent alert beep | No change | Battery needs recharging. Pumps will stop operating in approximately fifteen minutes unless unit is plugged into an AC outlet. |
| SEC PROGRAM | No change | Secondary program data is being entered while pump is running. Pump will remain in SEC PROGRAM alert condition until SEC START key is pressed. |
| SEC RATE=0 | No flow | A secondary flow rate of zero has been entered. The pump will remain in this alert condition until a non-zero secondary flow rate is entered and the SEC START key is pressed. |
| SEC COMPLETE with intermittent alert beep | Secondary switches to primary | The secondary infusion is complete and the pump has switched back to the primary program. To exit this alert condition, press any key that is accepted for the pump (including unlocking the panel) while the SEC COMPLETE message is displayed. |
| SEC VTBI=0 | No flow | A secondary VTBI of zero has been entered. The pump will remain in this alert condition until a non-zero secondary VTBI is entered and the SEC START key is pressed. |
| FLOW RATE | No flow | During Volume-Time Programming, if a flow rate outside the device's capabilities is calculated, the message Hi or Lo will be displayed in the rate display. If an attempt is made to start the pump with either of these messages displayed, a FLOW RATE alert will be triggered. To exit this alert condition, reprogram the pump for a rate within the range selected through the configuration option and press the appropriate START key. |
| CHECK VTBI | No flow | A VTBI outside the acceptable range has been entered. To exit this alert condition, enter a VTBI within the range selected through the configuration option and press the appropriate START key. |

Technical Specifications

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|---------------------------|---|
| Catalog Code Number | 2M8048 |
| Description | Dual channel linear peristaltic volumetric infusion pump |
| Administration Set | Baxter standard administration sets with "s" suffix |
| Keep Vein Open (KVO) Rate | 5 mL/hr or programmed rate, whichever is less |
| Nurse Call | Standard feature that can be activated by authorized service personnel. |
| Battery | 12 Volt, 3.2 Ah sealed lead acid |
| Battery Life | -Approximately 6 hours with one pump running at a rate from 1 to 1400 mL/hr -Approximately 4 hours with both pumps running at rates from 1 to 1400 mL/hr |
| Battery Recharge | 8 hours for complete recharge |
| AC Power Requirements | 110/120V, 60 Hz |
| Power Cord | 2.9 m (9 ft) long, with Hospital Grade plug |
| Fuse | 0.75 A, 250V, SB, 6.35 mm (1/4 in) x 31.8 mm (1-1/4 in) |
| Leakage Current | Less than 50 microamps (using UL-544 specified test methods) |
| Weight | Approximately 8.2 kg (18 lbs) |
| Dimensions | 33 cm W x 21 cm D x 29 cm H (13" W x 8.3" D x 11.4" H) |

Notes: The remainder of the specifications listed here can be set by authorized service personnel to best suit the requirements of the hospital.

To view the settings, press TIME and TOT VOL/STATUS simultaneously for one second while both pumps are stopped. The message CONFIGURE will appear in the Pump 1 message display. A parameter description will appear in the first line of the Pump 2 message display, and the setting will appear in the second line. The SEC START key will access each setting consecutively. To exit the inspection mode, press TIME and TOT VOL/STATUS simultaneously.

If there is any question regarding the device's current settings or applicability for a particular clinical application, the operator and facility professionals should verify that the settings are appropriate. The configuration settings can be changed *only* by authorized service personnel.

| | |
|-----------------------|--|
| Flow Rate Range | Primary program: 1 - 1999 mL/hr in 1 mL increments on each channel. Upper limit can be set by authorized service personnel. Secondary program: 1 - 999 mL/hr in 1 mL increments on each channel. |
| VTBI Range | 1 - 9999 mL for both primary and secondary of each channel. Upper limit can be set by authorized service personnel. |
| Air-in-Line Detection | Factory set to NORM, which causes the device to alarm on air bubbles approximately 75 μ L or larger. The MIN setting causes the device to alarm on air bubbles approximately 50 μ L or larger. |
| Occlusion Detection | The occlusion level setting is displayed momentarily after the self test when the device is first powered on. This setting, which represents the initial distal occlusion alarm pressure, is factory set to LEVEL 1. The possible settings are: LEVEL 1 (approximately 7 psi (362 mm Hg)) LEVEL 2 (approximately 12 psi (620 mm Hg)) LEVEL 3 (approximately 17 psi (879 mm Hg)) |

Warranty And Service Information

Warranty

Baxter Healthcare Corporation warrants that the equipment shall be free from defects in material and workmanship when delivered to the original purchaser. Baxter Healthcare Corporation's sole obligation shall be limited to repair or replacement, at Baxter's option and expense, of the defective part or unit for a period of one year following the date of initial delivery. Warranty for the replaceable battery pack is limited to a period of six months under normal use and service.

THERE ARE NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY AND ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WHICH EXTEND BEYOND THE DESCRIPTION OF THE PRODUCT AND THOSE EXPRESSLY SET FORTH IN ITS LABELING. UNLESS USED ACCORDING TO THE DIRECTIONS ACCOMPANYING THE PRODUCT, ALL WARRANTIES ARE SPECIFICALLY EXCLUDED. In no event shall Baxter Healthcare Corporation be responsible for incidental, consequential or exemplary damages. Modification, alteration, recalibration or abuse, and service by other than a Baxter Healthcare Corporation authorized representative may void the warranty.

Service Information

While under Baxter Healthcare Corporation Warranty, Service Agreement (optional), or lease agreement, the instrument must not be opened by unauthorized personnel.

To contact Baxter Healthcare Corporation Customer Service Division for service and repair information for all instruments, call 1-(800) THE PUMP.

Shipping costs for all units returned to Baxter Healthcare Corporation shall be paid by the customer. The unit must be packed in its original container or in another Baxter approved container that will provide adequate protection during shipment. To ensure prompt return, a Baxter Product Service representative must be notified before shipping any unit for repair. When calling Baxter Product Service, please be prepared to provide code number and serial number of the unit. A service request number will be issued and should accompany all communications. A brief written description of the problem should be attached to the instrument when it is returned for service.

Baxter Healthcare Corporation will not be responsible for unauthorized returns or for units damaged in shipment due to improper packing.

